

REMARKS

Claims 2-10 and claims 58-61 are pending in the present application. Claims 1, and 11-57 were canceled as they are drawn to a non-elected invention. Applicants retain the right to file a continuation and/or a divisional application to any canceled claims. Claims 58-61 are added. Support for claims 58-61 can be found on page 8, lines 24-27; page 11, lines 8-29; and page 12, lines 1-4 and lines 9-23. No new matter has been added.

The issues outstanding in this application are as follows:

- Claims 2-10 were rejected under 35 U.S.C. § 101 as allegedly lacking an specific or well-established utility.
- Claims 2-10 were rejected under 35 U.S.C. § 112, first paragraph.

Applicants respectfully traverse the outstanding rejections, and Applicants respectfully request reconsideration and withdrawal thereof in light of the amendments and remarks contained herein.

I. Rejection under 35 U.S.C. § 101

Claims 2-10 are rejected under 35 U.S.C. § 101 as lacking a specific or well established utility. Applicants respectfully traverse.

Under the utility guidelines, the initial burden is on the Patent Office to establish a *prima facie* case of utility, which requires sufficient evidentiary basis. According to MPEP 2107.02, where the asserted utility is not specific or substantial, a *prima facie* showing contains the following:

- 1) An explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is neither both specific and substantial nor well-established;
- 2) Support for factual findings relied upon reaching this conclusion; and
- 3) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

Applicants assert that the Office has not properly established a *prima facie* case. For example, the Office states that all the asserted utilities that it lists by page and line number are general utilities and are not considered specific or substantial because there is no disclosed signaling pathway associated with SEQ.ID.NO. 1 or that there is not specific disease or cell-proliferative disorder associated with SEQ.ID.NO. 1. Applicants respectfully traverse.

As defined in the specification, SEQ.ID.NO. 1 is an ovary specific polynucleotide sequence, as indicated by Figures 7 and 8. Thus, one of skill in the art would understand that any cell proliferative disorder or disease associated with SEQ.ID.NO. 1 would be related to an ovary type disease or disorder. Such diseases are listed in the specification, for example, page 3, lines 8-9, which includes ovarian tumors, such as germ cell tumors and granulosa cell tumors, infertility, such as premature ovarian failure.

Still further, the Application states on page 7, lines 5-14 that the expression of SEQ.ID.NO. 1 is similar to that of GDF-9, which is known to play a role in fertility. The Application continues to suggest that blocking the expression of SEQ.ID.NO.1 would result

in a contraceptive action. The expression of SEQ.ID.NO. 1 is shown in Example 3, page 25, lines 1-12, which shows that mRNA encoded by SEQ.ID.NO. 1 is expressed in oocytes of primary and preantral follicles through ovulation. With the expression being specific to the oocytes, one of skill in the art would know that this polynucleotide and products thereof would play a role in oogenesis or folliculogenesis, more specifically fertility.

To provide further evidence in support of the asserted utility, Applicants submit a declaration by one of the inventors, as well as a published manuscript in the journal *Nature Genetics*. The declaration and published manuscript further confirms the evidence in the specification that SEQ.ID.NO. 1 is involved in fertility.

In view of the above statements, Applicants assert that the specification does disclose how to use the polynucleotide and thus, sets forth a specific and substantial utility and/or a well-established utility. If, however, the Examiner continues to maintain a *prima facie* case of non-utility, then the Applicants respectfully request that the above criteria be indicted in the next Action, more specifically support for factual findings relied upon in reaching this conclusion; and an evaluation of all relevant evidence of record, including utilities taught in the closest prior art. Applicants remind the Examiner that if the Office cannot develop a proper *prima facie* case and provide evidentiary support for a rejection under 35 U.S.C. 101, then a rejection on this ground should not be imposed. See, for example, *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

II. Rejection under 35 U.S.C. § 112

Claims 2-10 are rejected under 35 U.S.C. § 112, first paragraph since the claimed invention lacks a specific or well established utility. Applicants respectfully traverse.

Applicants assert that the claimed invention has an asserted utility as discussed above. Thus, in view of the above comments, Applicants request that the rejection be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P01925US1 from which the undersigned is authorized to draw.

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Respectfully submitted,

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